

Introducing Project Management and Emotional Intelligence to Statistical Programmers

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ABSTRACT

In the era of collaboration among sponsors and functional service providers, statistical programmers not only need to know analysis and reporting methodologies for clinical trials, but also must manage timelines, oversee qualities, deliver through others, and manage stakeholder expectations. This paper discusses a training we have developed for our Study Lead Programmers on Project Management. Fundamental principles in Project Management including stakeholder management, risk assessment and mitigation are taught and discussed in the training. We have also used this training to introduce Emotional Intelligence and the mindset of the Lean Methodology. We will share our experiences on how this training has had a positive impact to the day-to-day work. Furthermore, we will discuss the next steps on how to continue to enhance the skills and cultivate the mindset of the lead programmers in order to better manage their projects.

Key Words: Statistical Programmer, Project Management, Emotional Intelligence, lean methodology, Risk Management, Stakeholder Management

INTRODUCTION

Globalization increases the need for interaction and collaboration among workforces. Increased pressure to reduce cost has driven pharmaceutical companies to look for more efficient and effective ways for clinical development through partnering with CROs and functional service partners. This new era of collaboration and interaction calls for additional skills for statistical programmers to manage scope and timelines, oversee quality, deliver through others and manage customer expectations.

As statistical programmers working on clinical trial analysis and reporting, whether one admits it or not, we use project management skills in our daily work.

In 2017 we introduced a suite of lead programmer training which covers the following topics:

- Fundamentals of Project Management
- Lean Methodology
- Emotional Intelligence
- Stakeholder Management
- Risk Management

FUNDAMENTALS OF PROJECT MANAGEMENT

A project is a temporary endeavor to create a unique product, service or result. A project has a defined beginning and end as well as a defined scope and a set of available resources. What makes project management challenging is that each project has unpredictable elements. Good project managers plan and manage in ways that can reduce this 'unpredictability' factor.

TRIPLE CONSTRAINTS

Every project, regardless of industry, has three constraints that affect quality.

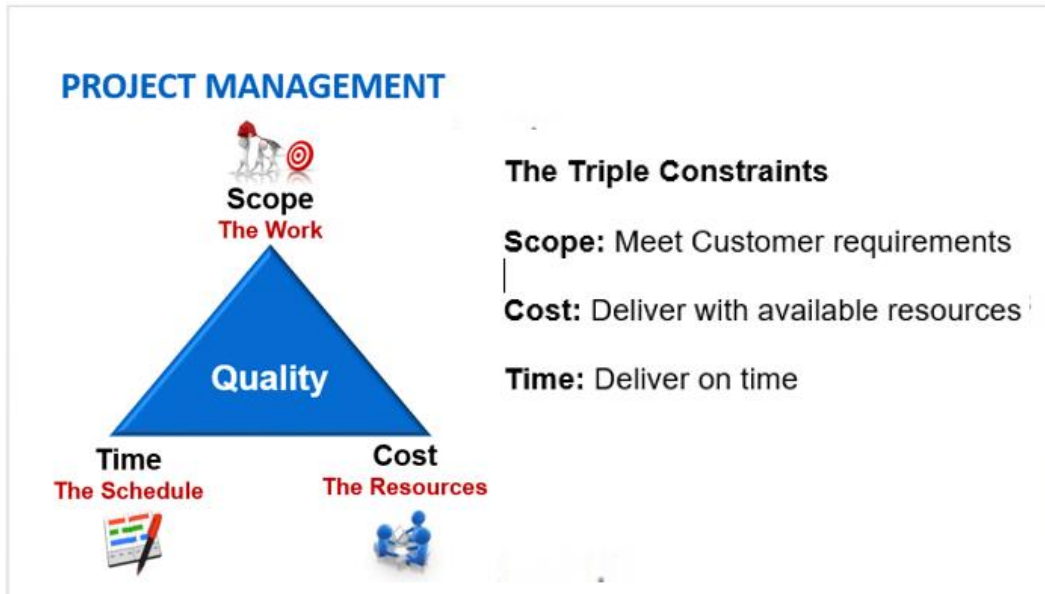


Figure 1

Scope, Cost and Time impact each other. If one or more constraints changes, other constraints may be impacted. Ultimately, quality may be jeopardized if any of the triple constraints are not stable.

In order to achieve quality and customer satisfaction, we must constantly weigh the priorities - for example, shorter schedule, increased effort or reduced scope.

SCOPE

Scope is defined as the work that will meet project requirements. It is the most important aspect of the project to define during the early planning phase. Once the scope is clearly defined, other project aspects such as schedule, resourcing, stakeholders and risks can then be assessed. If the requirements are not clearly defined initially, we will most likely have to deal with issues such as scope-creep, re-work, frustration and stakeholder tensions. Scope management is important to ensure cost, timeline and quality. As a study lead programmer, we need to influence, interact and negotiate with our stakeholders to contain the scope and avoid unnecessary analysis. Refer to the later sections on Stakeholder Management and Lean Methodology for the Elimination of Waste.

COST

Cost, in our case, refers to the available resources (Statistical Programmers) to perform the required work. Once the scope is defined and stabilized, we can then allocate the appropriate resources.

When faced with constrained resources, make sure the scope is well contained and plan your resources before the actual work begins. Detailed planning is critical. For example, borrowed resources can help to some degree, as long as there is sufficient time to bring them up to speed. Consider discussing this option with your stakeholders when defining the scope and timeline of the project.

Managing stakeholder expectations and ensuring they are on message early in the process will help stabilize the scope and therefore, your planned resources.

Statistical Programming is a highly skilled profession, developing your team becomes the key to the project.

Rather than think, 'I need an A-team for this project', actively build an A-Team. Resist the urge to

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do the work for them, unless absolutely necessary. By spending more time coaching and guiding, you also get to know their strengths and limitations. This will help you make smarter resourcing decisions for future projects. Another goal of coaching is to build knowledge among your team members, so they can work independently and delivery quality work. As the lead, create an environment that embraces and praises innovation, particularly in ways that reduce waste and add value to the project. Finally, build in critical thinking skills so everyone is an investigator of their own work. Socialize mistakes without the blame. Foster a learning-centered environment.

People are capable of creating, learning, adapting and overcoming obstacles through problem-solving and working smarter and safer. Empower the people who do the work and their ingenuity will eliminate waste and lead to better outcomes.

TIME

Time refers to the schedule. Every project has a deadline. As a lead programmer, we need to deliver our project on time once it's negotiated and decided.

A milestone is a significant event or point in the project to be achieved and has zero duration in the schedule. Depending on the complexity of the project, you may need to build many or just a few milestones in your schedule. Consider building them first before you schedule and allocate resources. Take a look at some typical programming milestones that we incorporate into our project schedules.

- Protocol date
- First subject enroll date
- SAP date
- TFL (Tables, Figures and Listings) Shell available date
- Draft TFL date
- Database lock date
- TFL package delivery date

Once you know the final due date, you can work backwards to schedule milestones leading towards the programming deliverables.

CRITICAL PATH

Critical Path is the longest sequence of activities that must be completed on time for the project to finish on schedule. Any tasks on the critical path that are delayed or takes longer to complete will move out the project end date. That is why it is important to monitor critical path activities.

LEAD TIME (OR CYTEL TIME)

Lead Time or Cycle Time is the time from initiation to the completion of the project. Think about your projects and ask yourself if the lead time for any of these projects could have been shortened. Was too much time wasted in obtaining programming requirement? Was too much time used in re-work and corrections? Perhaps too much time was used to develop more tables than necessary. Were there too many unforeseen issues that popped up and had to be resolved? By asking and thinking through these types of questions, you are on your way to a leaner and more strategic approach to project management.

LEAN METHODOLOGY¹

"Lean" was first used to describe the Toyota Production System (TPS). TPS has the goal of delivering goods and services of the highest quality at the lowest cost in the shortest lead time, which means higher value for the customers. "Lean" is based on creating a culture on how one responds to a problem rather than what tool one uses.

The principles of lean include:

- Customer first – Understand what is of the most value to the customers. This directly addresses the constraint of Scope.
- Trusting and respecting each other – Build the best team; Respect your people. If we do this right, the Cost constraint can be well managed since in the world of Statistical Programming, resource (people) is the cost.
- Continuous Improvement – Build a learning-centered environment. Through the practice of continuous improvement, we can build knowledge, be more efficient, and work smarter

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- without burning people out.
- Eliminating waste – Eliminate unnecessary work or unnecessary processes. When you are facing choices, always ask the question 'is it necessary?'. Through identifying and eliminating wasteful things, we can improve quality and shorten the lead time.

People work on wasteful items without often realizing it. We can group most of the waste into seven types:

- 1) Overproduction
Overproduction is producing too many items or producing items too early. This is the worst type of waste. It drives all the other wastes.
- 2) Waiting
Waiting means people are idle. They cannot move on to the next task. This is the easiest waste to resolve. All we need to do is re-allocate people to value adding tasks. However, this can still be challenging because quite often we don't have transparency into what tasks people are performing and what it actually takes to complete the tasks.
- 3) Conveyance (Or Transportation)
Conveyance or transportation involves moving materials or output unnecessarily. It can also be to move the surplus material to make room.
- 4) Inventory
Too much work in progress, often as a result of overproduction. This is mostly a result of the inability to understand customer demand and aligning our processes to effectively meet that demand with minimal waste. Not all inventory is bad! Good inventory is inventory that is justified because we understand fluctuations and or risks in demand
- 5) Over-Processing
Doing more than necessary within a step. This is often a result of an unclear expectation. Therefore extra 'padding' is added just in case.
- 6) Motion
Unnecessary movement of people. For example, people try to locate misplaced document or seek unnecessary approvals.
- 7) Correction (Rework, Mistake)
Correction (rework, mistake) is the seventh waste and it's the most difficult to see because errors are not predictable. They impact directly to quality and lead to the other types of waste listed above.

Waste can be difficult to see.

- People appear to be busy.
- Sub-optimization of functional group processes vs. optimizing entire value streams.
- Comfort in legacy systems and old ways.
- The common misconception of 'more is better'.
- Staff members are not convinced if the process is good.
- Staff members do not know what the standards are.

EMOTIONAL INTELLIGENCE

Strong project managers possess strong people skills. Effective stakeholder management requires leadership and emotional intelligence. After all, we are not in the business of simply taking orders. Much more is involved in dealing with our stakeholders, many of whom also need to manage their own set of customers.

Emotional intelligence is the ability to recognize and manage your own emotions as well as the emotions of others to ultimately manage relationships more effectively. In practical terms, this means being aware that emotions can drive behavior and impact people - positively and negatively - and learning how to manage those emotions (our own and others) especially when we are under pressure. Some experts believe that EI, or EQ, Emotional Quotient, is a better indicator of personal and business success than IQ. The good news is that while you are born with your IQ, you can develop your EQ.

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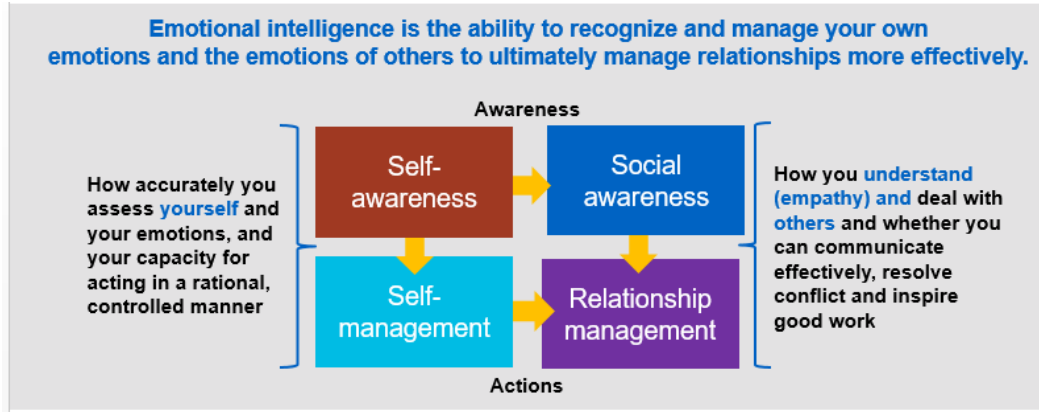


Figure 2

It all begins with **YOU**. Figure 2 shows that awareness of self and others allows you to manage yourself and others. Self-awareness and self-management are indicators of how accurately you assess yourself and your emotions, and your capacity to act in a rational, controlled manner. Social awareness and relationship management are indicators of how well you empathize with others and whether you can communicate effectively, resolve conflict and inspire good work. Appropriate awareness is necessary for appropriate action.

Let's discuss five strategies to increase your emotional intelligence.

1. Study others who possess a high 'EQ.' Read up on the topic. In other words, heighten your awareness.
2. Get feedback, understand the feedback and own it. Don't find excuses for your behavior because that defeats the purpose of getting feedback. Keep in mind, feedback can be informal. All feedback, even if you don't agree with it totally, is useful and contributes to self-awareness and understanding others' perceptions of your actions.
3. Be aware of the gap between intent and impact - what you mean to say and what others actually hear. This gap tends to happen especially in tense situations or in a heated discussion. Sometimes people blurt out things because they are afraid of losing control. Be aware when you are feeling frustrated or impatient. Those are the times when it is more likely your intent will be different from the impact.
4. Don't forget that you have choices about how to respond to people and situations.
5. We often hear "put yourself in the other person's shoes" but don't ignore how YOU feel. What does your gut say? Wear both shoes to understand your agenda and theirs.

STAKEHOLDER MANAGEMENT

Stakeholder management is not just about knowing who our stakeholders are. It is really about relationship management, a dynamic, ongoing process that often extends beyond a project start and end date.

Stakeholders are the people affected directly and/or indirectly by the work you and your team produces. It is important to be aware that stakeholders can also influence our projects in both positive and negative ways.

Stakeholder management refers to managing communications to satisfy the needs of, and resolve issues with, project stakeholders. Actively managing stakeholders increases the likelihood that the project will not veer off track due to unresolved stakeholders issues, enhances the ability of people to operate synergistically, and limits disruptions during the project.

Stakeholder influence changes over the life of the project. Early in the project, changes typically cost less to implement. Later, as more of the project work is done, changes typically increase in cost. Remember, cost can refer to resource. Our strategy is to engage stakeholder early. This means understanding expectations, negotiating timelines, gaining input into specifications and requirements as soon as possible.

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Here are some questions to consider, especially for our challenging stakeholders.

- What are their short-term and long-term goals and do we have a plan to help them meet these goals?
- Are their expectations reasonable given the timeline and resources on hand? How can we influence them?
- How can we get them to help us succeed
- What information will they give us?
- What is their communication style? Formal or informal? Collaborative or authoritative?
- And finally, are they willing to take risks?

NEGOTIATION

Generally, we think of negotiation when faced with the risk of not completing the project or request on time or within scope or when we are faced with a mission impossible. Because projects operate within the limits of finite resources which require allocation among priorities, project managers should negotiate constantly! In fact, you may be negotiating often, you just don't realize it. Asking simple questions such as "why do you need this" or "what's this for?" represents the beginning of possible negotiations.

Negotiation is a dialogue between multiple parties to reach a mutually beneficial outcome where conflict exists, often involving concessions and trade-offs with respect to scope, time, cost and quality. The goal is to achieve a solution that satisfies all parties involved. Keep the 'bigger picture' in mind. We are all on the same 'Team'. Beware that negotiating too hard to achieve functional targets - a personal win - could derail the whole project or weaken strong stakeholder alliances.

Let's review some good practices when negotiating with stakeholders.

- Set a positive tone. Remember the social awareness quadrant of emotional intelligence.
- Discuss your expectations regarding the negotiation process. People often have different assumptions about how the negotiation should work. Some expect proposals to be made at the outset, while others anticipate an open discussion of the issues first. Make sure that all parties have a shared understanding of the process.
- Offer information.
- Allow your stakeholders to express their position or request. It is easy to get bogged down by the details of what they want but start with the big picture first and find out why they want what they are requesting.
- Communicate the impact of their request to the scope, timeline, resources and quality.
- Every project has potential risks. Communicate to the stakeholders about the risks and mitigate the risks together as a team.

Keep in mind that you can and should escalate to the next level if we cannot reach an agreement with the stakeholders.

RISK MANAGEMENT

Risk vs. Issue

A risk is a possible future event or circumstances that can have a negative influence on a project. For example, a group of new programmers coming from a different therapeutic area could be a possible risk.

An issue, on the other hand, is a risk that has occurred. For example, mistakes are found in the TFL post-delivery to the team, which requires amending.

Trying to track and manage issues is not the right approach - although it can be all too common. It is human nature to want to move forward and make progress rather than think of ways to prevent something that may or may not happen.

The goal of managing risks proactively is so they don't turn into issues that will consume our time and resources. Managing risks involves identifying, assessing, mitigating and tracking the risks. Use the Risk Assessment Matrix (Figure 3) to assess each risk based on the probability of it occurring and the level of impact if it turns into an issue.

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Risk Assessment Matrix				
Probability	High	Median	High	High
	Med	Low	Median	High
	Low	Low	Low	Median
		Low	Med	High
		Impact		

Figure 3

Refer to Figure 3 for the risk assignment of 'High', 'Median' and 'Low'. Prioritize the mitigation strategies according to the overall risk level.

Periodically monitor the risks as new risks could be added and the categories for the existing risks could change.

SUMMARY

We introduced the following trainings on project Management in the context of Statistical Programming in the second half of 2017:

- The Principles of Project Management
- Emotional Intelligence and Stakeholder Management
- Introduction to Lean Methodology

Early feedback was very positive. Since methodologies contain a lot of common sense, adoption was not a problem. As a result, the training has leveled the playing field. People have been able to discuss projects with the same language in project management and apply the learning into their day-to-day work. For example the lead programmers learned the importance of involving their stakeholders early to discuss risks and mitigation plans.

Each of the topics above have more branches, e.g. the Value Stream Mapping in Lean, the leadership behaviors in Emotional Intelligence. We believe through continued learning and ongoing practice, the organization will be able to cultivate a culture of learning and continuous improvement².

REFERENCES

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RECOMMENDED READING

- Lean Thinking: Banish Waste And Create Wealth In Your Corporation
- Emotional Intelligence: Why It Can Matter More Than IQ
- The Seven Habits of Highly Effective People

CONTACT INFORMATION

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¹For more details on lean, please refer to the PharmaSUG2018 Conference Proceedings for the paper titled 'Framework for Critical Thinking – Introducing Lean Philosophy to Statistical Programmers' by Wenyun Ji.

²The time between the training and this paper is not long enough to collect more quantitative metrics. We will continue to bring the learnings to the staff members and monitor the success of the training.